UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

February 5, 2013

MEMORANDUM

Subject: Efficacy Review for Super-Chlor, EPA Reg. No. 69687-1; DB Barcode: D406078.

From: Ibrahim Laniyan, Ph.D.
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To: Eliza Blair / Monisha Harris PM 32 Monisha Harris 2-12-13
Regulatory Management Branch II
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Applicant: Medtrol, Inc.
7157 North Austin Avenue
Niles, IL 60714

Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium hypochlorite	0.65 %
Other ingredients*	99.35 %
Total	100.00 %

* Other Ingredients do not include the weight of towelette.

I. BACKGROUND

The product, Super-Chlor (EPA Reg. No. 69687-1), is an EPA-approved disinfectant (bactericide, fungicide, and virucide) for use on hard, non-porous surfaces in institutional, and hospital or medical environments. The applicant requested, to amend the registration of this product to increase the percentage of Sodium hypochlorite from 0.525% to 0.65%, and to add claims for effectiveness as a disinfectant against Hepatitis C virus and spores of *Clostridium difficile*. The label states that the product is effective in the presence of 5% blood serum. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated September 27, 2012), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-27 (Formulators' Exemption Statement), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-35 (Data Matrix), Six studies (MRID 489534-01 through 489534-06), Statements of No Data Confidentiality Claims for all studies, and the proposed label (dated 09-27-2012).

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: blood glucose meters, carts, cellular phones, counters, examination tables, headsets, patient care equipment, sinks, stethoscopes, telephones, and toilet seats. The proposed label does not identify the types of surfaces on which the product may be used (e.g., stainless steel, glass). Directions on the proposed label provide the following information regarding use of the product as a disinfectant: Thoroughly clean gross filth and heavy soil from surfaces prior to disinfection. Apply towelette and wipe desired surface. Allow treated surfaces to remain thoroughly wet for 5 minutes (3 minutes against *Clostridium difficile* spores and 30 seconds against Hepatitis C virus). Allow surface to air dry.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sporicidal Disinfectant against *Clostridium difficile*: The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following two test methods: AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); and ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The toxigenic strains, ATCC 43598, of *Clostridium difficile* must be used for testing. All products must carry a pre-cleaning step. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. Control carrier counts must be greater than 10^6 spores/carrier.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides - Use of a Surrogate Virus: For certain viruses, there are no *in vitro* systems or *in vivo* animal models (except for humans and chimpanzees). The Agency permits the testing of surrogate viruses in these cases, for example, Bovine viral diarrhea virus as a surrogate for human Hepatitis C virus, Duck Hepatitis B virus as a surrogate for Human Hepatitis B virus, and Feline calicivirus as a surrogate for Norwalk virus.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. BRIEF DESCRIPTION OF THE DATA

Note: The following product lots were reported to contain the associated percentage of chlorine before testing:

F04EXP0513, 6082 ppm NaOCl (0.64%)
G25EXP0613 and G26EXP0613, 6149 ppm NaOCl (0.65%)
F16EXP0513, 6216 ppm NaOCl (0.65%)
F17EXP0513, 6171 ppm NaOCl (0.65%)
E22EXP0413, 6193 ppm NaOCl (0.65%)
E23EXP0413, 6216 ppm NaOCl (0.65%)

1. MRID 489534-01 "Wetness Determination for Towelette Products", by Becky Lien. Study conducted at ATS Labs. Study completion date – September 5, 2012. Project Number A13811.

The purpose of this study was to determine the residual wetness of test carriers following treatment and a 5 minute contact time. Three lots (Lot Nos. F04EXP0513, G25EXP0613, and G26EXP0613) of the product, Super-Chlor, were tested using ATS Labs protocol # MRL01070212.WET (copy provided) for observing and measuring the surface wetness imparted by simulated use of towelettes. The lot, F04EXP0513, was ≥60 days aged. The product was received as a ready to use wipe. One towelette was used to wipe a glass (12 inch X 12 inch) carrier per lot of test substance. The test carriers were wiped with a damp cloth and allowed to air dry prior to initiation of the study in order to remove dust. Three (3) towelettes were

evaluated per lot. A video recorder was used to record the procedure from the start to finish. Prior to treatment, the carrier was weighed. The towelette was folded in half twice, once along the length and once along the width. The towelette was placed on the top left corner of the test carrier and wiped in an up and down motion, each stroke slightly overlapping the last, until the entire test carrier was completely covered for approximately 7 total strokes. A calibrated timer was initiated after the entire test surface was treated. The carrier was placed on the scale, the initial wet weight of carrier was taken, the carrier was allowed to be undisturbed for the exposure period of 3 minutes, and upon completion of the exposure period the final wet weight was taken. The test surface was wiped across a single sheet of unfolded cigarette paper immediately following final weighing to assist in visualization of wetness. Visual wetness of the cigarette paper was used to determine the presence or absence of carrier wetness.

For the gravimetric wetness test, one towelette was used to wipe 10 glass slide carriers for each lot under ambient conditions. Prior to wiping, the carriers were dried for 30 minutes at approximately 105°C and cooled for at least one hour prior to being weighed. The towelette was folded in half lengthwise twice and rolled five times and each carrier in its empty aluminum weigh boat without a lid was weighed. Each carrier was wiped and immediately weighed. The exposure period of 3 minutes began once the carrier was wiped. Each carrier was weighed after the exposure period. Following, the carriers were dried for 30-37 minutes at approximately 105°C and cooled for at least one hour prior to being re-weighed The acceptance criterion for this procedure is that the weight following the exposure time is greater than the dried weight for all carriers tested.

Note: For the Gravimetric Wetness Confirmation calculation of the percentage of moisture loss, the following calculation was applied:

Percent (%) Moisture Loss = $[1- (W_f - W_d) / (W_w - W_d)] \times 100$

W_d = Dried weight of treated slide
W_w = Weight of slide immediately following wiping
W_f = Final weight of slide following exposure time

Note: Protocol amendments and deviations reported in the study were reviewed.

Note: The applicant provided the data for one failed trial. In that trial, the final wet weight was not recorded. Thus, the test was invalid. These data were not used to determine wetness of carriers. See Attachments I, on page 16 of the laboratory report.

2. MRID 489534-02 "Pre-Saturated Towelettes for Hard Surface Sporicidal Activity" Test Organism: *Clostridium difficile* - spore form (ATCC 43598) for Super-Chlor, by Becky Lien. Study conducted at ATS Labs. Study completion date – August 31, 2012. Project Identification Number A13813.

The study was conducted against *Clostridium difficile* - spore form (ATCC 43598). One lot of the product Super-Chlor, Lot F04EXP0513, was tested using ATS Laboratory Protocol No. MRL01070212.STOW.1 (copy provided). The lot was ≥60 days aged. The product lot testing substance was received as a ready to use wipe. The spore purity was examined by Malachite green stain and microscopic analysis and found to be at a 92% spore to vegetative cell ratio. Glass slides (3 inch X 1 inch) were inoculated with 10 µL of culture that was uniformly spread over an approximate area of 1 inch X 1 inch and the inoculated slides were dried for 40 minutes at 35-37°C with 40% relative humidity. One towelette was used to wipe 10 carriers by folding in half lengthwise twice and rolled up five times prior to use. The wiping procedure was done by exposing the maximum amount of the towelette surface area and passing it over the carrier

surface back and forth twice for a total of four (4) passes for each inoculated carrier. The carriers were exposed for a 3 minutes contact period at 19°C with 60% relative humidity. Afterwards, each carrier was transferred to the primary subculture, 40 mL of C Diff Broth + 0.1% Sodium Thiosulfate, then to a secondary subculture, 40 mL of C Diff Broth. The wetness of each carrier was examined by two technicians prior to subculturing and found to remain wet during the testing period. The plates were incubated for 48±4 hours at 35–37°C under anaerobic conditions. All subculture vessels were incubated for 21 days at 35–37°C under anaerobic conditions prior to visual examination for the presence or absence of growth. Subcultures showing growth were subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included purity, sterility, viability, HCl resistance, carrier population, and neutralization.

Note: For the HCl resistance control assay, four inoculated and dried carriers were transferred to vessels containing 40 mL of 2.5N HCl at room temperature and one carrier per time period was incubated for either 2 minutes, 5 minutes, 10 minutes, or 20 minutes prior to transferring each to primary vessels containing 40 mL of Modified Fluid Thioglycollate medium and secondary vessels containing 40 mL of Modified Fluid Thioglycollate medium. The vessels were incubated with the test vessels. The acceptance criterion is to observe growth after at least 2 minutes of exposure.

3. MRID 489534-03 "Pre-Saturated Towelettes for Hard Surface Sporicidal Activity" Test Organism: *Clostridium difficile* - spore form (ATCC 43598) for Super-Chlor, by Becky Lien. Study conducted at ATS Labs. Study completion date – September 4, 2012. Project Identification Number A13814.

The study was conducted against *Clostridium difficile* - spore form (ATCC 43598). One lot of the product Super-Chlor, Lot G25EXP0613, was tested using ATS Laboratory Protocol No. MRL01070212.STOW.2 (copy provided). The product lot testing substance was received as a ready to use wipe. The spore purity was examined by Malachite green stain and microscopic analysis and found to be at a 92% spore to vegetative cell ratio. Glass slides (3 inch X 1 inch) were inoculated with 10 µL of culture that was uniformly spread over an approximate area of 1 inch X 1 inch and the inoculated slides were dried for 40 minutes at 35-37°C with 40% relative humidity. One towelette was used to wipe 10 carriers by folding in half lengthwise twice and rolled up five times prior to use. The wiping procedure was done by exposing the maximum amount of the towelette surface area and passing it over the carrier surface back and forth twice for a total of four (4) passes for each inoculated carrier. The carriers were exposed for a 3 minutes contact period at 20°C with 60% relative humidity. Afterwards, each carrier was transferred to the primary subculture, 40 mL of C Diff Broth + 0.1% Sodium Thiosulfate, then to a secondary subculture, 40 mL of C Diff Broth. The wetness of each carrier was examined by two technicians prior to subculturing and found to remain wet during the testing period. The plates were incubated for 48±4 hours at 35–37°C under anaerobic conditions. All subculture vessels were incubated for 21 days at 35–37°C under anaerobic conditions prior to visual examination for the presence or absence of growth. Subcultures showing growth were subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included purity, sterility, viability, HCl resistance, carrier population, and neutralization.

Note: For the HCl resistance control assay, four inoculated and dried carriers were transferred to vessels containing 40 mL of 2.5N HCl at room temperature and one carrier per time period was incubated for either 2 minutes, 5 minutes, 10 minutes, or 20 minutes prior to transferring each to primary vessels containing 40 mL of Modified Fluid Thioglycollate medium and

secondary vessels containing 40 mL of Modified Fluid Thioglycollate medium. The vessels were incubated with the test vessels. The acceptance criterion is to observe growth after at least 2 minutes of exposure.

4. MRID 489534-04 "Pre-Saturated Towelettes for Hard Surface Sporicidal Activity" Test Organism: *Clostridium difficile* - spore form (ATCC 43598) for Super-Chlor, by Becky Lien. Study conducted at ATS Labs. Study completion date – August 31, 2012. Project Identification Number A13815.

The study was conducted against *Clostridium difficile*- spore form (ATCC 43598). One lot of the product Super-Chlor, Lot G26EXP0613, was tested using ATS Laboratory Protocol No. MRL01070212.STOW.3 (copy provided). The product lot testing substance was received as a ready to use wipe. The spore purity was examined by Malachite green stain and microscopic analysis and found to be at a 92% spore to vegetative cell ratio. Glass slides (3 inch x 1 inch) were inoculated with 10 µL of culture that was uniformly spread over an approximate area of 1 inch x 1 inch and the inoculated slides were dried for 40 minutes at 35-37°C with 40% relative humidity. One towelette was used to wipe 10 carriers by folding in half lengthwise twice and rolled up five times prior to use. The wiping procedure was done by exposing the maximum amount of the towelette surface area and passing it over the carrier surface back and forth twice for a total of four (4) passes for each inoculated carrier. The carriers were exposed for a 3 minutes contact period at 19°C with 61% relative humidity. Afterwards, each carrier was transferred to the primary subculture, 40 mL of C Diff Broth + 0.1% Sodium Thiosulfate, then to a secondary subculture, 40 mL of C Diff Broth. The wetness of each carrier was examined by two technicians prior to subculturing and found to remain wet during the testing period. The plates were incubated for 48±4 hours at 35–37°C under anaerobic conditions. All subculture vessels were incubated for 21 days at 35–37°C under anaerobic conditions prior to visual examination for the presence or absence of growth. Subcultures showing growth were subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included purity, sterility, viability, HCl resistance, carrier population, and neutralization.

Note: For the HCl resistance control assay, four inoculated and dried carriers were transferred to vessels containing 40 mL of 2.5N HCl at room temperature and one carrier per time period was incubated for either 2 minutes, 5 minutes, 10 minutes, or 20 minutes prior to transferring each to primary vessels containing 40 mL of Modified Fluid Thioglycollate medium and secondary vessels containing 40 mL of Modified Fluid Thioglycollate medium. The vessels were incubated with the test vessels. The acceptance criterion is to observe growth after at least 2 minutes of exposure.

5. MRID 489534-05 "Pre-Saturated Towelettes for Hard Surface Sporicidal Activity" Test Organism: *Clostridium difficile* - spore form (ATCC 43598) for Super-Chlor, by Becky Lien. Study conducted at ATS Labs. Study completion date – June 28, 2012. Project Identification Number A13385.

The non-GLP study was conducted against *Clostridium difficile* - spore form (ATCC 43598). One lot of the product Super-Chlor, Lot D02EXP0313, was tested using ATS Laboratory Protocol No. MRL01042312.STOW (copy not provided). The product lot testing substance was received as a ready to use wipe. Glass slides (3 inch x 1 inch) were inoculated with spore preparation. One towelette was used to wipe 10 carriers. The wiping procedure was done by exposing the maximum amount of the towelette surface area and passing it over the carrier surface back and forth twice for a total of four (4) passes for each inoculated carrier. The

carriers were exposed for 3 minutes or 5 minutes contact time at 21°C. Afterwards, each carrier was transferred to the primary subculture of C Diff Broth + 0.1% Sodium Thiosulfate, then to a secondary subculture of Modified Fluid Thioglycollate + 0.1% Cholic Acid. The plates were assayed for survivors. Controls included purity, sterility, viability, HCl resistance, carrier population, and neutralization.

Note: For the HCl resistance control assay, four inoculated and dried carriers were transferred to vessels containing 40 mL of 2.5N HCl at room temperature and one carrier per time period was incubated for either 2 minutes, 5 minutes, 10 minutes, or 20 minutes prior to transferring each to primary vessels containing 40 mL of Modified Fluid Thioglycollate medium and secondary vessels containing 40 mL of Modified Fluid Thioglycollate medium. The vessels were incubated with the test vessels. The acceptance criterion is to observe growth after at least 2 minutes of exposure.

6. MRID 489534-06 "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus" for Super-Chlor, by Shanen Conway. Study conducted at ATS Labs. Study completion date – June 29, 2012. Project Number A13369.

This study was conducted against Bovine Viral Diarrhea Virus (BVDV, obtained from National Veterinary Services Laboratories, Ames, IA) as a Surrogate Virus for Human Hepatitis C Virus, using bovine turbinate cells (BT cells – ATCC CRL-1390) as the host system. Two lots (F16EXP0513 and F17EXP0513) of Super-Chlor were tested according to ATS Labs Protocol No. MRL01043012.BVD (copy provided). The stock virus culture was adjusted to contain 1% horse serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus film was wiped in two sections with the towelettes over and back two times for a total of four passes (one carrier with one towelette). Carriers were then held covered for 30 seconds at 22.0°C. Following exposure, 2 ml of test medium (Minimum Essential Medium (MEM) with 5% non-heat inactivated horse serum glucose, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B) was added to each plate and scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in test medium. BT cells in multi-well culture dishes were inoculated in quadruplicate with 0.1mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. On the final day of incubation, the cultures were immunofluorescently (direct) stained or labeled with a fluorescein conjugated antibody specific to DVDV. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber and by the Most Probable Number statistics using the template provided by Big Sky Statistical Analysts LLC (Bozeman, MT).

Note: Protocol amendment reported in the study was reviewed.

Note: The applicant provided the data for one failed trial. In that trial, the numbers controls were below the required number (4 logs). Thus, the tests were invalid. These data were not used to evaluate efficacy of the test product. See Attachments I (for testing conducted on June 1, 2012) of the laboratory report.

V. RESULTS

MRID Number	HCL Resistance Control 0 = No Growth + = Growth 1° = Primary Culture 2° = Secondary Culture								No. Exhibiting Growth/ Total No. Tested			Control Carrier Population (Average log_{10})
	Minutes of exposure								F04EXP 0513 (≥60 days aged)	G25EXP 0613	G26EXP 0613	
	2		5		10		20		3-Minutes Exposure Period			
	1°	2°	1°	2°	1°	2°	1°	2°				
489534-02	0	+	0	+	0	+	0	+	1° = 0/60 2° = 0/60	---	---	6.32
489534-03	0	+	0	+	0	+	0	+	---	1° = 0/60 2° = 0/60	---	6.10
489534-04	0	+	0	+	0	+	0	+	---	---	1° = 0/60 2° = 0/60	6.27
									Time	D02EXP0313 (≥60 days aged)		
489534-05	0	+	0	+	0	+	0	+	3 min	1° = 0/30	2° = 0/30	6.40
									5 min	1° = 0/30	2° = 0/30	

MRID 489534-01	Gravimetric Wetness (Avg. % Moisture Loss) (Pass/Fail)* 3 minutes exposure	Visual Wetness Determination 3 minutes exposure period			
		Initial Weight of Carrier	Initial Wet Weight of Treated Carrier	Final Wet Weight of Treated Carrier	Visual Wetness on Cigarette Paper (Pass/Fail)†
F04EXP0513	3.5% (Pass)	512.81 g	513.37 g	513.07 g	Pass
G25EXP0613	3.7% (Pass)	512.48 g	513.00 g	512.75 g	Pass
G26EXP0613	4.0% (Pass)	510.80 g	511.23 g	511.04 g	Pass

***Passing results are demonstrated when the value for weight following the exposure time is greater than weight after drying.**

†Passing results are demonstrated when visual wetness observed on the cigarette paper.

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1mL)
		Description	F16EXP0513	F17EXP0513	
489534-06	Human Hepatitis C Virus (Bovine Viral Diarrhea Virus as surrogate)	10^{-1} to 10^{-4} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.5}$
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.0	≥4.0	

VI. CONCLUSION

1. The submitted efficacy data (MRID nos. 489534-01 through 489534-05) **do not support** the use of Super-Chlor as a disinfectant with sporicidal activity against *Clostridium difficile* spores on hard, non-porous surfaces for a contact time of 3 minutes at 20.0°C. **Efficacy data were generated using an unapproved method for testing towelette products against *C. difficile*.**

2. The submitted efficacy data (MRID 489534-06) **support** the use of Super-Chlor as a disinfectant with virucidal activity against Human Hepatitis C Virus (Bovine Viral Diarrhea Virus as surrogate) on **pre-cleaned** hard, non-porous surfaces for a contact time of 30 seconds at 20.0°C.

VI. LABEL

1. The Agency does not feel comfortable accepting qualitative efficacy methods when testing towelette products against *Clostridium difficile*. In the absence of a validated quantitative method mimicking the actual use of towelette products, the registrants are encouraged to submit protocol for review before testing. For the moment, the Agency accepts quantitative efficacy data generated using ASTM E 2197 with expressed liquid (at LCL) from towelette. Contact time is based on wetness determination test.

2. The Agency recognizes the confusion on determining the appropriate test method for the evaluation of towelette products against *C. difficile* spores. As it stands, claims of *Clostridium difficile* spores **are not fully** supported by the submitted efficacy data. **In order to fully support claims against *C. difficile* spores, registrant must submit a confirmatory efficacy data, using ASTM E 2197 with expressed liquid (at LCL), on one lot of the towelette product Super-Chlor.**

3. The proposed label claims that the product, Super-Chlor, is an effective **one-step** disinfectant with virucidal activity against Human Hepatitis C Virus (Bovine Viral Diarrhea Virus as surrogate) on hard, non-porous surfaces for a contact time of 30 seconds at 20.0°C, **are not supported** by the applicant's data. **Efficacy was generated in the presence of 1% horse serum. Efficacy must be generated in the presence of at least 5% organic load to be qualified one-step. Registrant must remove all one-step claims for Human Hepatitis C Virus (Bovine Viral Diarrhea Virus as surrogate) (see pages 5 and 7 of the proposed label). Pre-cleaning step must precede all Human Hepatitis C Virus (Bovine Viral Diarrhea Virus as surrogate) claims.**

4. The applicant must make the following changes to the proposed label, as appropriate:

- On page 1 of the proposed label, change **Other Ingredients' concentration to 99.35%.**
- On the proposed label, **remove all *Clostridium difficile* Spore claims until a submitted quantitative study on one lot of the product Super-Chlor is accepted.**
- After *Clostridium difficile* sporicide claims are approved, label must include these specific cleaning directions:

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed.

Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Data Submission: Information on the test system must be submitted including but not limited to the test design, spore production method, ATCC strain, spore titer, efficacy test method, neutralization study design and outcome, individual plate counts for treated and control carriers, and calculations including log reduction values. Any deviations to standard methods should be noted and supplied to the Agency. For the purpose of product registration, all studies are to be conducted following the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards, 40 CFR Part 160, including media quality assessments and spore production.